



PATENT  
ATTORNEY DOCKET NO. 01997/518004

Certificate of Mailing: Date of Deposit: 12/14/06

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Seth Eckstein

Printed name of person mailing correspondence

Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Mikos et al.	Confirmation No.:	8716
Serial No.:	10/775,768	Art Unit:	1651
Filed:	February 10, 2004	Examiner:	David M. Naff
		Customer No.:	21559
Title:	POROUS BIODEGRADABLE POLYMERIC MATERIALS FOR CELL TRANSPLANTATION		

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

REQUEST TO CORRECT INVENTORSHIP UNDER 37 C.F.R. § 1.48 (a)

Applicant hereby requests correction of inventorship in the above-captioned application from:

Antonios G. Mikos, Donald E. Ingber, Joseph P. Vacanti, and Robert S. Langer

to:

Antonios G. Mikos, Robert S. Langer, Joseph P. Vacanti, Linda G. Griffith, and Georgios Sarakinos.

Linda G. Griffith is formerly named Linda G. Cima.

The inventors set forth in the executed Declaration under 37 C.F.R. § 1.63 that was filed in this case on August 31, 2004 were in error. In support of this request, enclosed

are:

A statement from each person being added as an inventor (Griffith and Sarakinos) and the person being removed as an inventor (Ingber) that the error in inventorship occurred without deceptive intent, filed in U.S. Patent No. 6,689,608, formerly U.S. Application Serial No. 09/669,760 (Exhibits A-C).

Executed Declarations filed in U.S. Patent No. 6,689,608, formerly U.S. Application Serial No. 09/669,760, under 37 C.F.R. § 1.63 by the actual inventors (Exhibits D-H).

A check for \$130.00 for the fee required under 37 C.F.R. § 1.17(i).

A written consent of the assignee to this correction of inventorship, filed in U.S. Patent No. 6,689,608, formerly U.S. Application Serial No. 09/669,760 (Exhibits I and J).

A Request to Correct Inventorship under 37 C.F.R. § 1.48(a), filed in U.S. Patent No. 6,689,608, formerly U.S. Application Serial No. 09/669,760 (Exhibit K).

The above-referenced documents, submitted herewith, were originally submitted in the parent case Mikos et al. (U.S. Patent No. 6,689,608; hereafter “Mikos ‘608”, formerly U.S. Application Serial No. 09/669,760) of the present application (U.S. Application Serial No. 10/775,768), a continuation of U.S. Application Serial No. 09/669,760, was and should be applied for the reasons detailed below to the present application.

### *Prosecution History*

An incorrect Declaration was filed in the present case on August 31, 2004 (Exhibit L) in response to a Notice to File Missing Parts of Nonprovisional Application mailed on May 6, 2004 (Exhibit M). As a result of the August 31, 2004 Declaration being filed instead of the corrected Declaration, the inventorship of the present application was changed from the correct inventors “Antonios G. Mikos, Robert S. Langer, Joseph P. Vacanti, Linda G. Griffith, and Georgios Sarakinos,” as noted on the original cover sheet of the present application filed February 10, 2004 (Exhibit N), to “Antonios G. Mikos, Donald E. Ingber, Joseph P. Vacanti, and Robert S. Langer” as noted on the second filing receipt mailed on March 21, 2006 (Exhibit O).

### *Reasons for Correction*

As an initial matter, Applicants note that the disclosure of the present application is identical to that of the Mikos ‘608 application. In addition, we note that the Office has identified the subject matter of the independent claim of the present application as identical to the subject matter of the independent claim of its parent application through a Statutory-Type Double Patenting rejection (page 3 of Exhibit P). The correct inventors’ Declarations extend to “the subject matter described and claimed” in the parent application (Exhibits D-H) and the Office maintains that the subject matter of the present application and that of the parent application were directed to the same independent claim. The inventor to be deleted, Donald E. Inger, has disclaimed his inventorship in the parent application (Exhibit C) and the assignees have affirmed these corrections to inventorship in the parent application as well (Exhibits I and J). Applicants submit that the Declarations and Requests to Correct Inventorship (Exhibits A-K) originally applied to the claimed invention of the parent application (Mikos ‘608) are also applicable to the claimed invention of the present application. In light of these facts, please correct the inventorship of the present application by adding Linda G. Griffith and Georgios

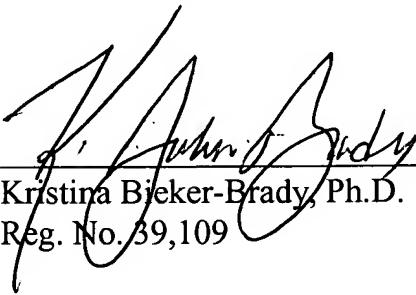
Sarakinos as inventors and by excluding Donald E. Ingber as an inventor in the present application, so that the corrective entity of the present application is "Antonios G. Mikos, Robert S. Langer, Joseph P. Vacanti, Linda G. Griffith, and Georgios Sarakinos" as indicated in the application as filed.

If there are any other charges or any credits, please apply them to Deposit Account No. 03-2095.

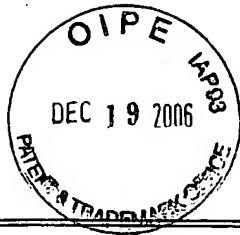
Respectfully submitted,

Date:

December 14, 2006

  
Kristina Bieker-Brady, Ph.D.  
Reg. No. 39,109

Clark & Elbing LLP  
101 Federal Street  
Boston, MA 02110  
Telephone: 617-428-0200  
Facsimile: 617-428-7045



# Exhibit A

PATENT

ATTORNEY DOCKET NO. 01997/518003

Certificate of Mailing: Date of Deposit: June 7, 2002

I hereby certify under 37 C.F.R. § 1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Rosemarie Perullo

Printed name of person mailing correspondence

Rosemarie Perullo

Signature of person mailing correspondence

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Antonios G. Mikos et al.

Art Unit: 1651

Serial No.: 09/669,760

Examiner: D.M. Naff

Filed: September 26, 2000

Customer No.: 21559

Title: POROUS BIODEGRADABLE POLYMERIC MATERIALS FOR  
CELL TRANSPLANTATION

Assistant Commissioner For Patents  
Washington, D.C. 20231

### REQUEST TO CORRECT INVENTORSHIPS -- DECLARATION OF INVENTOR ADDED

I, Georgios Sarakinos, hereby declare:

1. That I am an original inventor in the above-referenced patent application.

2. That through error and without any deceptive intent on my part, the above-

referenced application was filed naming "Antonios G. Mikos, Robert S. Langer, Donald

E. Ingber and Joseph P. Vacanti" rather than "Antonios G. Mikos, Robert S. Langer,

Joseph P. Vacanti, Linda G. Griffith and Georgios Sarakinos".

3. That I should be added as an inventor in the above-referenced application.

3. That I should be added as an inventor in the above-referenced application.

4. That all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date 24 May 2002



Georgios Sarakinos  
Keizer Karelplein 14  
6211 TC Maastricht  
The Netherlands

\Clark-w2k1\documents\01997\01997.518003 Decl. of Inv. to be added - GS.wpd



## Exhibit B

PATENT  
ATTORNEY DOCKET NO. 01997/518003

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Rosemarie Perullo

Printed name of person mailing correspondence

Rosemarie Perullo

Signature of person mailing correspondence

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Antonios G. Mikos et al.	Art Unit:	1651
Serial No.:	09/669,760	Examiner:	D.M. Naff
Filed:	September 26, 2000	Customer No.:	21559
Title:	POROUS BIODEGRADABLE POLYMERIC MATERIALS FOR CELL TRANSPLANTATION		

Assistant Commissioner For Patents  
Washington, D.C. 20231

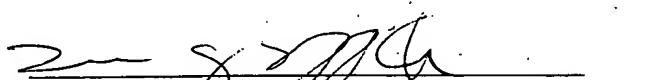
### REQUEST TO CORRECT INVENTORSHIPS -- DECLARATION OF INVENTOR ADDED

I, Linda G. Griffith, hereby declare:

1. That I am an original inventor in the above-referenced patent application.
2. That through error and without any deceptive intent on my part, the above-referenced application was filed naming "Antonios G. Mikos, Robert S. Langer, Donald E. Ingber and Joseph P. Vacanti" rather than "Antonios G. Mikos, Robert S. Langer, Joseph P. Vacanti, Linda G. Griffith and Georgios Sarakinos".
3. That I should be added as an inventor in the above-referenced application.

4. That all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date 4 June 2002

  
Linda G. Griffith (formerly Linda G. Cima)  
110 Antlrim Street  
Cambridge, MA 02139



# Exhibit C

PATENT

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Rosmarie Perullo

Printed name of person mailing correspondence

Rosmarie Perullo

Signature of person mailing correspondence

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Antonios G. Mikos et al.

Art Unit: 1651

Serial No.: 09/669,760

Examiner: D.M. Naff

Filed: September 26, 2000

Customer No.: 21559

Title: POROUS BIODEGRADABLE POLYMERIC MATERIALS FOR  
CELL TRANSPLANTATION

Assistant Commissioner For Patents  
Washington, D.C. 20231

### REQUEST TO CORRECT INVENTORSHIPS -- DECLARATION OF INVENTOR DELETED

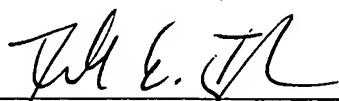
I, Donald Ingber, hereby declare:

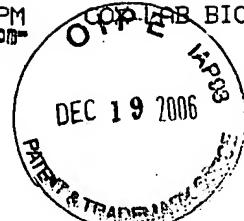
1. That I am named as an original inventor in the above-referenced patent application.
2. That through error and without any deceptive intent on my part, the above-referenced application was filed naming "Antonios G. Mikos, Robert S. Langer, Donald E. Ingber and Joseph P. Vacanti" rather than "Antonios G. Mikos, Robert S. Langer, Joseph P. Vacanti, Linda G. Griffith and Georgios Sarakinos".

3. That I should be deleted as an inventor in the above-referenced application.

4. That all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date 5/20/01

  
Donald E. Ingber  
71 Montgomery Street  
Boston, MA 02116



## Exhibit D

PATENT  
ATTORNEY DOCKET NO. 01997/518003Certificate of Mailing: Date of Deposit June 7, 2002

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Rosemarie Ferullo

Printed name of person mailing correspondence

Rosemarie Ferullo

Signature of person mailing correspondence

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Antonios G. Mikos et al. Art Unit: 1651  
Serial No.: 09/669,760 Examiner: David M. Naff  
Filed: September 26, 2000 Customer No. 21559  
Title: POROUS BIODEGRADABLE POLYMERIC MATERIALS FOR CELL TRANSPLANTATION

Assistant Commissioner of Patents and Trademarks  
Washington, DC 20231

DECLARATIONS OF ANTONIOS G. MIKOS, Sc.D., ROBERT S. LANGER, Sc.D.,LINDA G. GRIFFITH, Ph.D., and GEORGIOS SARAKINOS, Ph.D.

We declare:

1. We are inventors of the subject matter described and claimed in the above-captioned patent application.
2. We are inventors of the subject matter disclosed, but not claimed, in U.S.S.N. 08/012,270, now issued U.S. Patent No. 5,514,378.
3. At the time of invention of the subject matter described and claimed in the above-captioned patent application and invention of the claimed subject matter of U.S. Patent No. 5,514,378, we, Antonios Mikos, Robert Langer, Linda Griffith, and Georgios

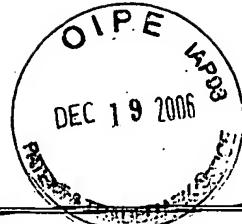
Sarakinos, had an obligation to assign our rights to Massachusetts Institute of Technology.

4. All statements made herein of my knowledge are true and all statements made on information and belief are believed to be true; and further these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date:

6/6/02

Antonios G. Mikos, Sc.D.



## Exhibit E

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Rosemarie Perullo

Printed name of person mailing correspondence

Rosemarie Perullo

Signature of person mailing correspondence

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Antonios G. Mikos et al. Art Unit: 1651  
Serial No.: 09/669,760 Examiner: David M. Naff  
Filed: September 26, 2000 Customer No. 21559  
Title: POROUS BIODEGRADABLE POLYMERIC MATERIALS FOR CELL TRANSPLANTATION

Assistant Commissioner of Patents and Trademarks  
Washington, DC 20231

DECLARATIONS OF ANTONIOS G. MIKOS, Sc.D., ROBERT S. LANGER, Sc.D.,LINDA G. GRIFFITH, Ph.D., and GEORGIOS SARAKINOS, Ph.D.

We declare:

1. We are inventors of the subject matter described and claimed in the above-captioned patent application.
2. We are inventors of the subject matter disclosed, but not claimed, in U.S.S.N. 08/012,270, now issued U.S. Patent No. 5,514,378.
3. At the time of invention of the subject matter described and claimed in the above-captioned patent application and invention of the claimed subject matter of U.S. Patent No. 5,514,378, we, Antonios Mikos, Robert Langer, Linda Griffith, and Georgios

Sarakinos, had an obligation to assign our rights to Massachusetts Institute of Technology.

4. All statements made herein of my knowledge are true and all statements made on information and belief are believed to be true; and further these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 5/28/02

RL

Robert S. Langer, Sc.D.



# Exhibit F

PATENT  
ATTORNEY DOCKET NO. 01997/518003

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Rosemarie Perullo  
Printed name of person mailing correspondence

Rosemarie Perullo  
Signature of person mailing correspondence

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Antonios G. Mikos et al. Art Unit: 1651  
Serial No.: 09/669,760 Examiner: David M. Naff  
Filed: September 26, 2000 Customer No. 21559  
Title: POROUS BIODEGRADABLE POLYMERIC MATERIALS FOR CELL TRANSPLANTATION

Assistant Commissioner of Patents and Trademarks  
Washington, DC 20231

DECLARATIONS OF ANTONIOS G. MIKOS, Sc.D., ROBERT S. LANGER, Sc.D.,

LINDA G. GRIFFITH, Ph.D., and GEORGIOS SARAKINOS, Ph.D.

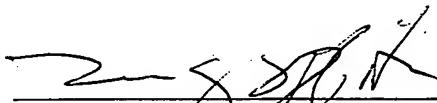
We declare:

1. We are inventors of the subject matter described and claimed in the above-captioned patent application.
2. We are inventors of the subject matter disclosed, but not claimed, in U.S.S.N. 08/012,270, now issued U.S. Patent No. 5,514,378.
3. At the time of invention of the subject matter described and claimed in the above-captioned patent application and invention of the claimed subject matter of U.S. Patent No. 5,514,378, we, Antonios Mikos, Robert Langer, Linda Griffith, and Georgios

Sarakinos, had an obligation to assign our rights to Massachusetts Institute of Technology.

4. All statements made herein of my knowledge are true and all statements made on information and belief are believed to be true; and further these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 4 June 2002

  
\_\_\_\_\_  
Linda G. Griffith, Ph.D.  
(formerly Linda G. Cima)

# Exhibit G

PATENT  
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Rosmarie Perullo

Printed name of person mailing correspondence

Rosmarie Perullo

Signature of person mailing correspondence

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Antonios G. Mikos et al.	Art Unit:	1651
Serial No.:	09/669,760	Examiner:	David M. Naff
Filed:	September 26, 2000	Customer No.	21559
Title:	POROUS BIODEGRADABLE POLYMERIC MATERIALS FOR CELL TRANSPLANTATION		

Assistant Commissioner of Patents and Trademarks  
Washington, DC 20231

### DECLARATIONS OF ANTONIOS G. MIKOS, Sc.D., ROBERT S. LANGER, Sc.D.,

LINDA G. GRIFFITH, Ph.D., and GEORGIOS SARAKINOS, Ph.D.

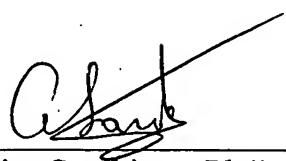
We declare:

1. We are inventors of the subject matter described and claimed in the above-captioned patent application.
2. We are inventors of the subject matter disclosed, but not claimed, in U.S.S.N. 08/012,270, now issued U.S. Patent No. 5,514,378.
3. At the time of invention of the subject matter described and claimed in the above-captioned patent application and invention of the claimed subject matter of U.S. Patent No. 5,514,378, we, Antonios Mikos, Robert Langer, Linda Griffith, and Georgios

Sarakinos, had an obligation to assign our rights to Massachusetts Institute of Technology.

4. All statements made herein of my knowledge are true and all statements made on information and belief are believed to be true; and further these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 24 May 2002

  
Georgios Sarakinis, Ph.D.



# Exhibit H

PATENT  
ATTORNEY DOCKET NO. 01997/518003

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Rosemarie Perullo

Printed name of person mailing correspondence

Rosemarie Perullo

Signature of person mailing correspondence

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Antonios G. Mikos et al.	Art Unit:	1651
Serial No.:	09/669,760	Examiner:	David M. Naff
Filed:	September 26, 2000	Customer No.	21559
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Assistant Commissioner of Patents and Trademarks  
Washington, DC 20231

### DECLARATION OF JOSEPH P. VACANTI, M.D.

I declare:

1. I am an inventor of the subject matter described and claimed in the above-captioned patent application.
2. I am an inventor of the subject matter disclosed, but not claimed, in U.S.S.N. 08/012,270, now issued U.S. Patent No. 5,514,378.
3. At the time of invention of the subject matter described and claimed in the above-captioned patent application and invention of the claimed subject matter of U.S. Patent No. 5,514,378, I, Joseph Vacanti, had an obligation to assign my rights to Children's Medical Center Corporation.

4. All statements made herein of my knowledge are true and all statements made on information and belief are believed to be true; and further these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 5/20/02

  
Joseph P. Vacanti, M.D.



# Exhibit I

PATENT  
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Rosemarie Penullo

Printed name of person mailing correspondence

Rosemarie Penullo

Signature of person mailing correspondence

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Antonios G. Mikos et al.	Art Unit:	1651
Serial No.:	09/669,760	Examiner:	D.M. Naff
Filed:	September 26, 2000	Customer No.:	21559
Title:	POROUS BIODEGRADABLE POLYMERIC MATERIALS FOR CELL TRANSPLANTATION		

Assistant Commissioner For Patents  
Washington, D.C. 20231

### REQUEST TO CORRECT INVENTORSHIP -- CONSENT OF ASSIGNEE

As an officer of the concern to which the above captioned application has been assigned, I hereby consent to the correction of inventorship of this application from:

--Antonios G. Mikos, Robert S. Langer, Donald E. Ingber and Joseph P. Vacanti--  
to:

"Antonios G. Mikos, Robert S. Langer, Joseph P. Vacanti, Linda G. Griffith and  
Georgios Sarakinos".

All statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements

are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 21 May 2002

Donald Lombardi

Donald P. Lombardi  
Chief Intellectual Property Officer  
The Children's Medical Center Corp.  
300 Longwood Avenue  
Boston, MA 02115



## Exhibit J

PATENT

ATTORNEY DOCKET NO. 01997/518003

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Rosemarie Perullo

Printed name of person mailing correspondence

Rosemarie Perullo

Signature of person mailing correspondence

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Antonios G. Mikos et al.

Art Unit: 1651

Serial No.: 09/669,760

Examiner: D.M. Naff

Filed: September 26, 2000

Customer No.: 21559

Title: POROUS BIODEGRADABLE POLYMERIC MATERIALS FOR  
CELL TRANSPLANTATION

Assistant Commissioner For Patents  
Washington, D.C. 20231

### REQUEST TO CORRECT INVENTORSHIP -- CONSENT OF ASSIGNEE

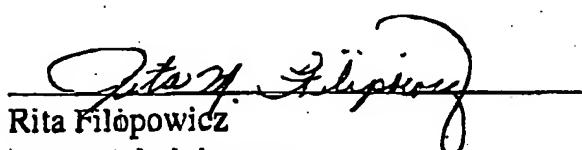
As an officer of the concern to which the above captioned application has been assigned, I hereby consent to the correction of inventorship of this application from:  
--Antonios G. Mikos, Robert S. Langer, Donald E. Ingber and Joseph P. Vacanti--  
to:

"Antonios G. Mikos, Robert S. Langer, Joseph P. Vacanti, Linda G. Griffith and  
Georgios Sarakinos".

All statements made herein of my own knowledge are true and that all statements

made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 6/5/02

  
Rita Filopowicz  
Patent Administrator  
Massachusetts Institute of Technology  
77 Massachusetts Avenue  
Cambridge, MA 02139-4307

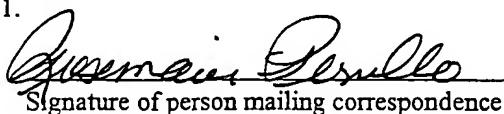
# Exhibit K

PATENT  
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Rosemarie Perullo  
Printed name of person mailing correspondence

  
Signature of person mailing correspondence

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Antonios G. Mikos et al.	Art Unit:	1651
Serial No.:	09/669,760	Examiner:	David M. Naff
Filed:	September 26, 2000	Customer No.:	21559
Title:	POROUS BIODEGRADABLE POLYMERIC MATERIALS FOR CELL TRANSPLANTATION		

Assistant Commissioner for Patents  
Washington, D.C. 20231

### REQUEST TO CORRECT INVENTORSHIP UNDER 37 CFR §1.48 (a)

Applicant hereby requests correction of inventorship in the above-referenced application from:

--Antonios G. Mikos, Robert S. Langer, Donald E. Ingber and Joseph P. Vacanti--

to:

“Antonios G. Mikos, Robert S. Langer, Joseph P. Vacanti, Linda G. Griffith and Georgios Sarakinos”.

The inventors set forth in the executed declaration under 37 C.F.R. § 1.63 filed January 23, 2001 were in error. In support of this request, enclosed are the following:

- A statement from each person being added as an inventor, executed by Linda G. Griffith and Georgios Sarakinos.
- A statement from each person being deleted as an inventor, executed by Donald Ingber.

- A newly executed Combined Declaration and Power of Attorney by Linda G. Griffith and Georgios Sarakinos.
- A consent of the assignee to this correction of inventorship executed by Rita Filipowicz and Donald Lombardi.
- A check for \$130.00 for the fee required under 37 C.F.R. § 1.17(i).

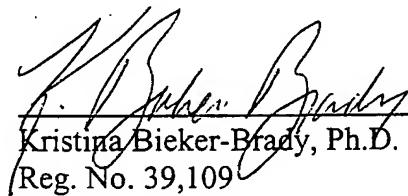
If there are any other charges, or any credits, please apply them to Deposit Account No.

03-2095.

Respectfully submitted,

Date:

June 7, 2002

  
Kristina Bieker-Brady, Ph.D.  
Reg. No. 39,109

Clark & Elbing LLP  
101 Federal Street  
Boston, MA 02110  
Telephone: 617-428-0200  
Facsimile: 617-428-7045



21559

PATENT TRADEMARK OFFICE

\Clark-w2k1\documents\01997\01997.518003 Req. Correct Invt. 1.48(a).wpd

# Exhibit L

## DECLARATION FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

I believe I am the original, first and sole inventor (if only one name is listed below), or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: **POROUS BIODEGRADABLE POLYMERIC MATERIALS FOR CELL TRANSPLANTATION**

the specification of which (check one)

       is attached hereto

was filed on April 23, 1993  
as application Serial No. 08/052,387

       and was amended on:       

(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, § 1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)	Priority Claimed
<u>      </u>	<u>      </u>
<u>      </u>	<u>      </u>
<u>      </u>	<u>      </u>

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of the application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Continuation-in-part US Serial No. <u>08/012,270</u> (Application Serial No.)	<u>February 1, 1993</u> (Filing Date)	Pending Status (patented, pending, abandoned)
<u>      </u>	<u>      </u>	<u>      </u>
<u>      </u>	<u>      </u>	<u>      </u>

"Porous Biodegradable Polymeric Materials for Cell Transplantation"

By: Antonios G. Mikos, et al.

Filed: April 23, 1993

DECLARATION

As named inventor, I hereby appoint the following attorney(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

John S. Pratt	29,476
James L. Ewing, IV	30,630
Patricia L. Pabst	31,284
Jamie L. Greene	32,467
Cheryl K. Zalesky	33,052
Dean W. Russell	33,452
Claudia R. Adkison	36,979
Charles T. Simmons	35,359

Send Correspondence to: Patrea L. Pabst, Esq.  
Kilpatrick & Cody  
1100 Peachtree Street, Suite 2800  
Atlanta, Georgia 30309-4530

Direct telephone calls to: Patrea L. Pabst (404)815-6508, or  
John S. Pratt (404)815-6367

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor Antonios G. Mikos

Inventor's signature \_\_\_\_\_ Date \_\_\_\_\_

Residence 4100 Greenbriar Drive, Apt. 345, Houston, Texas 77098

Citizenship Greece

Post Office Address Same as above

Full name of second joint inventor (if any) Donald E. Ingber

Inventor's signature D.E.I. Date 5/20/93

Residence 71 Montgomery Street, Boston, Massachusetts 02116

Citizenship United States

Post Office Address Same as above

"Porous Biodegradable Polymeric Materials

for Cell Transplantation"

By: Antonios G. Mikos, et al.

Filed: April 23, 1993

DECLARATION Full name of third joint inventor (if any) Joseph P. Vacanti

Inventor's signature Joseph P. Vacanti Date 5/8/93

Residence 14 Woodside Road, Winchester, Massachusetts 01890

Citizenship United States

Post Office Address Same as above

Full name of fourth joint inventor (if any) Robert S. Langer

Inventor's signature  Date

Residence 77 Lombard Street, Newton, Massachusetts 02158

Citizenship United States

Post Office Address Same as above

Full name of fifth joint inventor (if any)

Inventor's signature  Date

Residence

Citizenship

Post Office Address

Full name of sixth joint inventor (if any)

Inventor's signature  Date

Residence

Citizenship

Post Office Address

## "Porous Biodegradable Polymeric Materials for Cell Transplantation"

By: Antonios G. Mikell et al.

By: Attorneys for Plaintiff  
Filed: April 23, 1993

**DECLARATION**

As named inventor, I hereby appoint the following attorney(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

John S. Pratt	29,476
James L. Ewing, IV	30,630
Patrea L. Pabst	31,284
Jamie L. Greene	32,467
Cheryl K. Zalesky	33,052
Dean W. Russell	33,452
Claudia R. Adkison	36,979
Charles T. Simmons	35,359

Send Correspondence to: **Patrea L. Pabst, Esq.  
Kilpatrick & Cody  
1100 Peachtree Street  
Atlanta, Georgia 303**

Direct telephone calls to: Patrea L. Pabst (404)815-6508, or  
John S. Pratt (404)815-6367

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor Antonios G. Mikos

**Inventor's signature**

Date May 13, 1993

Residence 4100 Greenbriar Drive, Apt. 345, Houston, Texas 77098

## Citizenship Greece

Post Office Address      Same as above

Full name of second joint inventor (if any) **Donald E. Ingber**

**Inventor's signature**

Date \_\_\_\_\_

71 Montgomery Street Boston, Massachusetts 02116

Citizenship: United States

Re: Offer Address Same as above

"Porous Biodegradable Polymeric Materials  
for Cell Transplantation"

By: Antonios G. Mikos, et al.

Filed: April 23, 1993

DECLARATION

Full name of third joint inventor (if any) Joseph R. Vacanti

Inventor's signature Joseph R. Vacanti

Date 5/8/93

Residence 14 Woodside Road, Winchester, Massachusetts 01890

Citizenship United States

Post Office Address Same as above

Full name of fourth joint inventor (if any) Robert S. Langer

Inventor's signature Robert S. Langer

Date 6/16/93

Residence 77 Lombard Street, Newton, Massachusetts 02158

Citizenship United States

Post Office Address Same as above

Full name of fifth joint inventor (if any) \_\_\_\_\_

Inventor's signature \_\_\_\_\_

Date \_\_\_\_\_

Residence \_\_\_\_\_

Citizenship \_\_\_\_\_

Post Office Address \_\_\_\_\_

Full name of sixth joint inventor (if any) \_\_\_\_\_

Inventor's signature \_\_\_\_\_

Date \_\_\_\_\_

Residence \_\_\_\_\_

Citizenship \_\_\_\_\_

Post Office Address \_\_\_\_\_

# Exhibit M

f 2



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
10/775,768	02/10/2004	Antonios G. Mikos	01997/518004

### CONFIRMATION NO. 8716

21559  
CLARK & ELBING LLP  
101 FEDERAL STREET  
BOSTON, MA 02110

### FORMALITIES LETTER



\*OC000000012556104\*

Date Mailed: 05/06/2004

## NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

*Filing Date Granted*

### Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given TWO MONTHS from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.  
*Applicant must submit \$ 385 to complete the basic filing fee for a small entity.*
- The oath or declaration is missing.  
*A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.*
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(e) of \$65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

### SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **\$450** for a Small Entity

- \$385 Statutory basic filing fee.
- \$65 Late oath or declaration Surcharge.

Replies should be mailed to: Mail Stop Missing Parts  
Commissioner for Patents  
P.O. Box 1450  
Alexandria VA 22313-1450

*A copy of this notice **MUST** be returned with the reply.*

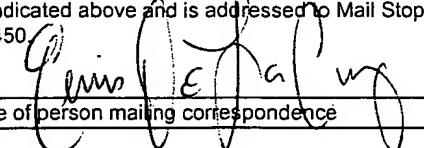
*Mosere Kenne*

Customer Service Center

Initial Patent Examination Division (703) 308-1202

PART 2 - COPY TO BE RETURNED WITH RESPONSE

# Exhibit N

Certificate of Mailing	
Date of Deposit: <u>February 10, 2004</u>	Label Number: <u>EV 232035151 US</u>
I hereby certify under 37 C.F.R. § 1.10 that this correspondence is being deposited with the United States Postal Service as "Express Mail Post Office to Addressee" with sufficient postage on the date indicated above and is addressed to Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
<u>Elvis De La Cruz</u> Printed name of person mailing correspondence	 Signature of person mailing correspondence

## APPLICATION FOR UNITED STATES LETTERS PATENT

APPLICANT : ANTONIOS G. MIKOS, ROBERT S. LANGER, JOSEPH P. VACANTI, LINDA G. GRIFFITH AND GEORGIOS SARAKINOS

TITLE : POROUS BIODEGRADABLE POLYMERIC MATERIALS FOR CELL TRANSPLANTATION

## Exhibit O

3



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
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 Alexandria, Virginia 22313-1450  
 www.uspto.gov

APPL NO.	FILING OR 371 (C) DATE	ART UNIT	FIL FEE REC'D	ATTY.DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/775,768	02/10/2004	1651	450	01997/518004	5	3	1

CONFIRMATION NO. 8716

21559  
 CLARK & ELBING LLP  
 101 FEDERAL STREET  
 BOSTON, MA 02110

UPDATED FILING RECEIPT



\*OC000000018325270\*

Docketing Required

Date Mailed: 03/21/2006

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

## Applicant(s)

Antonios G. Mikos, Houston, TX;  
 Donald E. Ingber, Boston, MA;  
 Joseph P. Vacanti, Winchester, MA;  
 Robert S. Langer, Newton, MA;

RECEIVED  
 MAR 28 2006

CLARK &amp; ELBING LLP

## Power of Attorney:

Paul Clark--30162	Susan Michaud--42885
Karen Elbing--35238	James DeCamp--43580
Mary Scozzafava--36268	
Kristina Bieker-Brady--39109	
Sean Edman--42506	

## Domestic Priority data as claimed by applicant

This application is a CON of 08/669,760 06/26/1996 PAT 5,610,753 \*  
 which is a CON of 08/052,387 04/23/1993 ABN  
 which is a CIP of 08/012,270 02/01/1993 PAT 5,514,378  
 (\*)Data provided by applicant is not consistent with PTO records.

## Foreign Applications

If Required, Foreign Filing License Granted: 05/06/2004

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US10/775,768**

**Projected Publication Date:** 06/29/2006

**Non-Publication Request:** No

**Early Publication Request:** No

**\*\* SMALL ENTITY \*\***

**Title**

Porous biodegradable polymeric materials for cell transplantation

**Preliminary Class**

435

## **PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES**

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

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### **LICENSE FOR FOREIGN FILING UNDER**

**Title 35, United States Code, Section 184**

**Title 37, Code of Federal Regulations, 5.11 & 5.15**

**GRANTED**

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

**NOT GRANTED**

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).



UNITED STATES PATENT AND TRADEMARK OFFICE

Exhibit P

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,768	02/10/2004	Antonios G. Mikos	01997/518004	8716
21559	7590	06/29/2006		
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			EXAMINER NAFF, DAVID M	
			ART UNIT 1651	PAPER NUMBER

RECEIVED

JUL 03 2006

CLARK & ELBING LLP

Please find below and/or attached an Office communication concerning this application or proceeding.

ACTION DUE Reply  
DUE DATE 9-29-06  
ESP 12-29-06  
INITIALS TM

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/775,768	MIKOS ET AL.
Examiner	Art Unit	
David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 10 February 2004.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 11-13 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) 11-13 is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on 10 February 2004 is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/23/05.

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_ .

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**DETAILED ACTION**

A preliminary amendment of 2/10/04 canceled claims 1-10, and added new claims 11-13.

A preliminary amendment of 6/14/04 amended the specification.

5 Claims examined on the merits are 11-13, which are all claims in the application.

***Specification***

The disclosure is objected to because of the following informalities: this application cannot be a continuation of parent 10 application 09/669,760 as stated in the first paragraph of the specification since this application has a different inventive entity from the parent application. An inventorship change should be made in this application as in the parent application. Furthermore, this application cannot be continuation of parent application 08/052,387 15 unless the inventorship change in 09/669,760 was also made in 08/052,387.

Appropriate correction is required.

It is noted that the Vacanti et al (Journal of Pediatric Surgery) listed on form 1449 has a publication date of Jan 98. However, patent 20 5,514,378 gives the date as 1988. Which is correct?

***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical 25 subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In*

Art Unit: 1651

re Ockert, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

5 A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

10 Claim 11 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,689,608 B1. This is a double patenting rejection.

Claim 11 is identical to that of claim 1 of the patent.

#### **Double Patenting**

15 The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the 20 conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 30 644 (CCPA 1969).

35 A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

40 Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12 and 13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-

Art Unit: 1651

7 of U.S. Patent No. 6,689,608 B1 in view of Vacanti et al (5,759,830).

The polymeric matrix of the claims of the patent is the same as presently claimed except for matrix comprising cells as required by 5 claim 12 and comprising a material enhancing cell attachment as required by claim 13.

Vacanti et al disclose attaching cells to a polymeric matrix. Different types of cells can be attached (col 6, lines 27-34), and the matrix can be coated with a coating that enhances cell attachment (col 10 10, lines 43-48).

Since the matrix of the patent claims is required by the claims to be suitable for attachment and proliferation of cells, it would have been obvious to attach to the matrix of the patent claims cells disclosed by Vacanti et al for attaching to a matrix. It would have 15 been further obvious to coat the matrix of the patent claims with a cell attachment enhancing coating as disclosed by Vacanti et al to obtain the attachment enhancing function of the coating.

#### *Double Patenting*

Claim 11 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,514,378. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent require a method for producing a porous biocompatible synthetic polymer membrane wherein crystallinity is 25 modified (claim 2), the membrane has a porosity of greater than 90%

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(claim 9), and particles are used that will produce a pore size of 100-500 microns (claim 4). When modifying the crystallinity as claimed by claim 2 of the patent, it would have been obvious to select a preferred optimum degree of crystallinity of 0-24.5% as presently 5 claimed. A membrane from the method of the patent claims having this crystallinity will be a matrix that is the same as the presently claimed matrix.

***Double Patenting***

Claims 12 and 13 are rejected on the ground of nonstatutory 10 obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,514,378 in view of Vacanti et al (5,759,830).

It would have been obvious to attach cells to the membrane resulting from the process of the patent claims to obtain the function of cells attached to the membrane as suggested by Vacanti et al when 15 attaching cells to a matrix since the membrane resulting from the method of the patent claims is biocompatible. Vacanti et al would have further suggested coating the membrane with a cell attachment enhancing coating as required by claim 13 to enhance cell attachment.

The patents listed on form PTO-892 other than applied are patents 20 made of record in parent application 09/669,760.

***Conclusion***

Any inquiry concerning this communication or earlier 25 communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

5 Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For 10 more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff  
Primary Examiner  
Art Unit 1651

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DMN  
6/23/09

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		10/775,768	MIKOS ET AL.	
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*	A US-5,736,372	04-1998	Vacanti et al.	435/180
*	B US-5,804,178	09-1998	Vacanti et al.	424/93.7
*	C US-5,759,830	06-1998	Vacanti et al.	435/180
*	D US-5,567,612	10-1996	Vacanti et al.	435/366
*	E US-5,770,193	06-1998	Vacanti et al.	424/93.7
*	F US-6,309,635	10-2001	Ingber et al.	424/93.7
*	G US-4,186,448	02-1980	Brekke, John H.	128/898
*	H US-5,514,378	05-1996	Mikos et al.	424/425
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Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.



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				Serial No.	10/775,768	
				Applicant	Antonios G. Mikos et al.	
				Filing Date	February 10, 2004	
				Group	1651	
				IDS Filed	June 21, 2005	
(37 C.F.R. § 1.98(b))						
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<i>gm</i>	Vacanti et al., Journal of Pediatric Surgery 23:3-9 (Jan 98)					
<i>gm</i>	Vacanti, Arch. Surg., 123:545-549 (1998)					
EXAMINER <i>gm</i>	DATE CONSIDERED 6/23/06					
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.						